

REMARKS

Reconsideration and allowance are respectfully requested.

Claims 34, 41-46 and 53-69 are pending.

The amendments are fully supported by the original disclosure and, thus, no new matter has been added. Applicants appreciate the Examiner's suggestions for amending the claims to overcome the Section 112 rejections. The priority claim has been updated to refer to the issued patent of a parent application and its PCT application.

35 U.S.C. 112 – Written Description

The specification must convey with reasonable clarity to persons skilled in the art that applicant was in possession of the claimed invention as of the filing date sought. See *Vas-Cath v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). The description includes "words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." *Lockwood v. American Airlines*, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). But the Patent Office has the initial burden of presenting evidence or a reason why persons of ordinary skill in the art would not have recognized such a description of the claimed invention in the original disclosure. See *In re Gosteli*, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

Claims 34, 41-46 and 53-57 were rejected under Section 112, first paragraph, because it was alleged that they contain "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Applicants traverse because amended claims 34 and 46 include the structural limitations of DNA constructs A and DNA construct B, respectively, as described in the specification (see below).

The Examiner objected at the bottom of page 4 of the Action, "There is no recitation in any of the rejected claims concerning the presence of recombinase recognition sequences on either side of the selectable drug-resistance gene having an mRNA-destabilizing sequence (e.g. for vectors corresponding to vector A or B of the instant specification), LTR sequences for those vectors corresponding to vector B of the instant

specification), and polyA sequences for either type of construct." He suggested at the top of page 7 of the Action that the claims can be amended "to include the structural limitations on page 14-line 16 to page 15-line 23 for DNA construct A or DNA construct B." Claims 34 and 46 are amended as suggested by the Examiner.

Withdrawal of the written description rejection made under Section 112, first paragraph, is requested because the specification conveys to a person skilled in the art that Applicants were in possession of the claimed invention as of the filing date.

35 U.S.C. 112 – Definiteness

Claims 56-57 were rejected under Section 112, second paragraph, as being allegedly "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Applicants traverse because claim 46 requires the expression vector comprise DNA construct B described in the specification.

Applicants request withdrawal of the Section 112, second paragraph, rejection because the pending claims are clear and definite.

35 U.S.C. 103 – Nonobviousness

To establish a case of prima facie obviousness, all of the claim limitations must be taught or suggested by the prior art. See M.P.E.P. § 2143.03. Obviousness can only be established by combining or modifying the prior art teachings to produce the claimed invention if there is some teaching, suggestion, or motivation to do so found in either the references themselves or in the knowledge generally available to a person of ordinary skill in the art. See, e.g., *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); *In re Jones*, 21 USPQ2d 1941, 1943-44 (Fed. Cir. 1992). It is well established that the mere fact that references can be combined does not render the resultant combination obvious unless the desirability of that combination is also taught or suggested by the prior art. See *In re Mills*, 16 USPQ2d 1430, 1432 (Fed. Cir. 1990). Thus, even if all elements of the claimed invention were known, this is not sufficient by itself to establish a prima facie case of obviousness without some evidence that one would have been motivated to combine

those teachings in the manner proposed by the Examiner. See *Ex parte Levengood*, 28 USPQ2d 1300, 1302 (B.P.A.I. 1993).

Evidence of the teaching, suggestion or motivation to combine or to modify references may come explicitly from statements in the prior art, the knowledge of a person of ordinary skill in the art or the nature of the problem to be solved, or may be implicit from the prior art as a whole rather than expressly stated in a reference. See *In re Dembiczak*, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999); *In re Kotzab*, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000). Rigorous application of this requirement is the best defense against the subtle, but powerful, attraction of an obviousness analysis based on hindsight. See *Dembiczak* at 1617. Whether shown explicitly or implicitly, however, broad conclusory statements standing alone are not evidence because the showing must be clear and particular. See *id.*

Claims 46 and 53-55 were rejected under Section 103(a) as allegedly unpatentable over Pavlakis et al. (U.S. Patent 5,972,596) in view of DePonti-Zilli et al. (Proc. Natl. Acad. Sci. USA 85:1389-1393, 1988). Applicants traverse.

Claims 46 and 53-55 were rejected under Section 103(a) as allegedly unpatentable over Pavlakis et al. (U.S. Patent 5,972,596) in view of Gritz et al. (Gene 25:179-188, 1983). Applicants traverse.

Claims 46 and 53-55 were rejected under Section 103(a) as allegedly unpatentable over Pavlakis et al. (U.S. Patent 5,972,596) in view of de la Luna et al. (Gene 62:121-126, 1988). Applicants traverse.

The claimed invention requires the presence of DNA construct B in the expression vector. In the description of the cited references on pages 8-16 of the Action, there is neither a teaching nor a suggestion of a first LTR, a packaging signal, a recombinase recognition sequence, etc. Therefore, the cited references do not establish a case of prima facie obviousness because all of the claim limitations must be taught or suggested by the prior art.

Withdrawal of the Section 103 rejections is requested because the invention as claimed would not have been obvious to a person of ordinary skill in the art at the time it was made.

35 U.S.C. 102 – Novelty

A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is claimed. See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 46 and 53-55 were rejected under Section 102(b) as allegedly anticipated by Schuler et al. (Cell 55:1115-1122, 1988). Applicants traverse.

It was asserted on page 16 of the Action that the cited reference describes fusion transcripts. There is no discussion therein, however, of an expression vector comprising DNA construct B as required by the claims.

Withdrawal of the Section 102 rejection is requested because all limitations of the claimed invention are not disclosed by the cited reference.

Double Patenting

Claims 34, 41-46 and 53-57 were rejected under the judicially-created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1, 6-7, 13, 16, 20 and 22-23 (U.S. Patent 6,743,620). Applicants traverse because a terminal disclaimer is submitted herewith.

It should be noted that the filing of a terminal disclaimer to overcome a rejection based on non-statutory double patenting is not an admission that the rejection was proper. See *Quad Environmental Technologies Corp. v. Union Sanitary District*, 20 USPQ2d 1392, 1394-95 (Fed. Cir. 1991). The Court stated that the "filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection." Thus, submission of a terminal disclaimer is not an admission that the pending claims are obvious over the claims of U.S. Patent 6,743,620.

Withdrawal of the double patenting rejection is requested.


Conclusion

Having fully responded to all of the pending objections and rejections contained in this Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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